US ERA ARCHIVE DOCUMENT

#### Memorandum

Date: February 13, 1981

Subject: EPA File Symbol: 4822-RIN RAID INDOOR FOGGER II

Caswell #844, 652B, 715, 670, 613

From: B. T. Backus

IRB/TSS

To: Mr. Franklin Gee

Product Manager 17

Applicant: S. C. Johnson & Son, Inc.

1525 Howe St. Racine, WI 53403

#### Active Ingredients:

Tetramethrin	0 . 540%
Sumithrin	0 387%
Related isomers	0 . 018%
Pyrethrins	0 . 050%
Piperonyl Butoxide (technical)	1 . 000%
N-octyl bicycloheptene dicarboximide	1 670%
Petroleum distillate	1 200%
Inert Ingredients:	95.135%

### Background:

Product is proposed as an indoor fogger for use in homes, apartments and restaurants. One can would treat a room of up to 6000 cubic feet. Directions specify to leave the home after activating fogger and to stay out of rooms being treated for at least two hours.

# Comments and Recommendations:

- 1. The oral LD50, dermal LD50, primary dermal and eye irritation studies submitted for this product are acceptable.
- 2. The eye irritation spray study has been classified as supplementary data as it is not certain as to what amount of material was actually sprayed in the rabbit eyes.
- 3. No inhalation LC50 study was submitted.
- 4. IRB/TSS would have no objections, on the basis of hazards to humans and domestic animals, to the conditional registration of this product for the proposed uses under the cite-all method of support and with the labeling revisions indicated below.

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## Labeling:

- 1. The subheading HAZARDS TO HUMANS should be expanded to HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
- 2. The statement under HAZARDS TO HUMANS AND DOMESTIC ANIMALS could be revised to something like:

CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly after handling. Do not remain in enclosed areas after use. Stay out of rooms being treated for at least two hours. Ventilate enclosed area before returning. Avoid contamination of food and food stuffs. All food preparation surfaces should be covered during application and thoroughly cleaned before use. Apply only when no food is being prepared. Remove pets, birds and cover fish aquariums before spraying.

3. There should be a STATEMENT OF PRACTICAL TREATMENT something like the following:

IF IN EYES: Flush with plenty of water. Get medical attention if irritation persists.

4. Revise "See Directions and Warnings on back to "See Directions and Carters on back."

Review:

The following studies were conducted at Raltech Scientific Services, P.O. Box 7545, Madison, WI 53707, using the product (identified as Formula 5198D45-2) as proposed for registration. Studies were received at EPA 12-9-80, and are in Acc. 244160.

1. Acute Oral Toxicity - Rat. RT Lab No. 800045. Report dated 09/09/80.

<u>Procedure</u>: 5M, 5F Sprague-Dawley rats, 235-290 g, received an oral dosage of 5 g/kg, with 14-day observation, survivor sacrifice and gross necropsy.

Results: No mortalities. Animals gained weight. Only symptoms reported were diarrhea in 2 subjects 1 hr after dosage. Necropsies were unremarkable. Rat oral LD50 greater than 5 g/kg.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. IV

2. Acute Dermal LD50 - Rabbit. RT Lab No. 800045. Report dated-09/09/80.

<u>Procedure</u>: 5M, 5F NZ white rabbits, dermally abraded, 2312-2930 g, received a 24-hr occluded dermal exposure to a dosage level of 2 g/kg, with 14-day observation, survivor sacrifice and gross necropsies.

Results: No mortalities. Subjects, on average, gained weight. Dermal LD50 above 2 g/kg. Necropsies unremarkable except for evidence of mild skin injury in 6/10 subjects.

Study Classification: Core Minimum Data (tested only at 2 g/kg).

Product Classification: Tox. Cat. III

3. Primary Skin Irritation - Rabbit. RT Lab No. 800045. Reported 09/09/80.

<u>Procedure</u>: 0.5 ml product was applied at each of 4 sites (2 intact, 2 abraded) on each of 6 NZ white rabbits, with 24-hr occluded exposure.

Results: Slight erythema (scores=1.0) in only 2 subjects at some sites at 24 hrs; however, all subjects showed erythema (max. score = 3) and edema (max. score = 2.5) at 72 hrs. Data suggest males are more susceptible than females. PDIS=1.73, but average dermal irritation at 3 days was 3.3.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. III (on basis of irritation at 72 hrs)

4. Eye Irritation - Rabbit. RT Lab No. 800045. Reported 09/09/80.

Procedure: 0.1 ml test material was instilled in one eye of each of 9 rabbits. 6 eyes remained unwashed; 3 were flushed with lukewarm water for one minute starting 30 seconds after instillation.

Results: 4/6 unwashed, 1/3 washed eyes showed slight conjunctival irritation at 24 hrs. At 72 hrs and subsequently all scores were zero.

Study Classification: Core Guideline Data

Product Classification: Tox. Cat. III

 Primary Eye Irritation Study - Sprayed - Rabbit. RT Lab No. 800085. Dated 10/21/80.

<u>Procedure</u>: 9 rabbits received a 2-second spray in one eye from a distance of four inches. 6 eyes remained unwashed; 3 eyes were flushed with lukewarm water for 1 minute starting 30 seconds after spraying.

Results: Slight conjunctival irritation in 1/6 unwashed, 0/3 washed eyes at 24 hrs. Eyes all clear at 48 hrs and subsequently.

Study Classification: Core Supplementary Data (no indication as to amount of material actually sprayed in eye).

Byran T. Backus

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